

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 20 DEC 2005

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Applicant's or agent's file reference BCS 03-5004 PCT		<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/EP2004/010985	International filing date (day/month/year) 29.09.2004		Priority date (day/month/year) 30.09.2003
International Patent Classification (IPC) or national classification and IPC C12N5/10, A01H5/00, C12N15/82, C12N9/10			
Applicant BAYER CROPSCIENCE GMBH et al.			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> ( <i>sent to the applicant and to the International Bureau</i> ) a total of sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> ( <i>sent to the International Bureau only</i> ) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).			
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application			
Date of submission of the demand 07.07.2005		Date of completion of this report 21.12.2005	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Holtorf, S Telephone No. +31 70 340- 	

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/010985

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-71 as originally filed

**Claims, Numbers**

1-34 as originally filed

**Drawings, Sheets**

143-43/43 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* *If item 4 applies, some or all of these sheets may be marked "superseded."*

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	18-21,24,25
	No: Claims	1-17,22,23,26-34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-34
Industrial applicability (IA)	Yes: Claims	1-34
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

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**Supplemental Box relating to Sequence Listing**

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**Continuation of Box I, item 2:**

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
  - a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form
  - c. time of filing/furnishing:  
 contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purposes of search and/or examination  
 received by this Authority as an amendment on
2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

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**1. The following documents are considered relevant for the current application:**

D1: WO0170942

D2: WO9634968

D3: EMBL database, Accession No. BG886850

D4: UniProt Database, Acc. No. Q8GWK4 & EMBL database Acc. No. AK118785

D5: Larsson, C-T., et al., 1998, PMB, 37, 3, pp. 505-511

D6: Mizuno, K., et al., 1993, 268, 25, pp. 19084-19091

**Re Item V.**

**2. Novelty and Clarity (Art. 33(2) and Art. 6 PCT)**

2.1 The current application is dealing with the provision of a method for the modification of the amylose/amyopectin ratio in transgenic plants through reducing the activity of a potato "Class 3 branching enzyme".

2.2 As currently drafted, Claim 1 and all claims depending thereon or referring thereto refer to a "genetically modified plant cell" wherein the genetic modification is not further specified and could also be achieved by the use of essentially biological processes like ordinary plant breeding or the selection for mutant plants exhibiting a certain phenotype. Furthermore, said wording does not essentially relate to a plant which has been transformed with a nucleotide sequence encoding a branching enzyme but does indeed refer to any modification leading to an decrease in the activity of said branching enzyme. Such modifications of the activity of the branching enzyme can alternatively obtained through the modulation of transcription factors or any other gene/protein interacting in the broadest possible sense with said branching enzyme. Moreover, the term "class 3 branching enzyme" is an internal designation for the identified potato-specific branching enzyme as characterized by SEQIDs 4 and 6. The use of the term "class 3 branching enzyme" is - if not further specified - completely misleading with respect to enzyme-terminology used in documents D5 and D6. The expression "reduced activity" in claim 1 is not further specified and open to any interpretation.

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2.3 In this respect, any document relating to the antisense expression of any branching enzyme in transgenic plants is novelty destroying for said claims. Document D1 (WO0170942) is disclosing the alteration of the amylose/amyllopectin ratio in plants by expressing an antisense construct of a potato branching enzyme leading to a high amylose starch. SEQID1 from this patent exhibits 56% identity in 1278 base pairs to SEQID3 and SEQID5 of the current application.

Accordingly, the subject matter of claims 1-17,22,23,26-34 is not novel over the prior art with respect to Art. 33(2) PCT.

2.4 WO9634968 (D2) discloses transgenic plants harbouring an antisense construct of a class A starch branching enzyme (SBE). The corresponding SEQID 13 of document D2 exhibits 56% and 55% identity in 1282 base pairs overlap to SEQID3 and SEQID5, respectively, of the current application. The starch with altered properties is analysed. Due to the lack of any other information characterizing the starch as defined in claims 26-34, said starch as defined in D2 is considered to have the same properties as the starch in claims 26-34.

Consequently, subject matter relating to the starch, the methods for the manufacture of said starch and the use of said modified starch as in claims 26-34 lack novelty over the prior art with respect to Art. 33(2) PCT.

2.5 When strictly interpreting claims 4g) and 15g), the subject matter of said claims relates to "fragments" and/or "derivatives" of the nucleic acid molecules as defined under a)-e) and f). Such "fragments" are not further defined and could consist of one or two base pairs only.

2.6 The format of the product claims 26, 32, 33 is unusual. The format is a "product-by-process" format, however, the product steps indicated do not necessarily lead to the product as claimed.

Product claims, as a general rule and if the application allows it, should be defined by the technical features of the product and not by process features.

**3. Inventive Step (Art.33 (3) PCT)**

3.1 Document D1 is considered to represent the closest prior art and discloses the generation of transgenic potato plants with a modified amylose/amyllopectin ratio by utilizing an antisense construct of a branching enzyme.

3.2 The difference between D1 and the current application is the use of another potato-specific nucleotide sequence encoding a branching enzyme.

3.3 The problem of the current application is the provision of an alternative branching enzyme for the modulation of the amylose/amyllopectin ration in plants.

3.4 The solution is the provision of potato-specific nucleotide sequences encoding a putative branching enzyme as characterized by SEQIDs 3,5 and 4,6, respectively.

3.5 Methods for using potato branching enzymes for the modulation of the amylose/amyllopectin ratio in transgenic plants are already known, see D1 and D2. Furthermore, alternative nucleotide sequences encoding alternative branching enzymes are also known, see D4 and D4. Document D3 is disclosing an EST sequence that exhibits 99% identity in 640 Bp to SEQIDs 3 and 5. Faced with the identified problem to provide alternative potato-specific nucleotide sequences encoding branching enzymes, the person skilled in the art would undoubtedly have screened the publicly available sequence databases and come across the EST sequence as defined in D3. Said EST sequence can easily be used as a tool to probe potato cDNA libraries and to finally isolate the respective full-length cDNA. The use of the gene to generate antisense transgenic plants and evaluate the effect of the respective enzyme on the amylose/amyllopectin ratio in said plants is obvious in the light of the prior art and not inventive.

Accordingly, the subject matter as defined in claims 1-34 lacks an inventive step according to Art.33 (3) PCT.